XI. 510(k) Summary

APR - 2 2001

K010412

PG. 1 OF 1

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, TeleMed Systems, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." TeleMed Systems chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name:	**TeleMed Systems Flexible Endoscopic Scissors**
Owner/Operator:	TeleMed Systems, Inc. 8 Kane Industrial Drive Hudson, MA 01749
Manufacturing Site:	TeleMed Systems, Inc. 8 Kane Industrial Drive Hudson, MA 01749
Device Generic Name:	**Flexible Endoscopic Scissors**
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (78KOG).
Predicate Devices:	Surgical Scissors marketed by Olympus Corp of America Cuschieri Scissors marketed by Karl Storz Endoskope

Product Description:
The TeleMed Systems Flexible Endoscopic Scissors are reusable, metallic surgical scissors that may be passed through a gastrointestinal endoscope and used to incise tissue.

Indications for Use:
The TeleMed Systems, Inc. Flexible Endoscopic Scissors are indicated for use for cutting of tissue when used through the working channel of a flexible or rigid endoscope.

Safety and Performance:
Substantial equivalence for these devices was based solely on design characteristics; no performance or safety data was included in this premarket notification. The materials, performance specifications and essential design characteristics of the TeleMed Systems device are substantially equivalent to those of the predicate devices.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the TeleMed Systems, Inc. Flexible Endoscopic Scissors have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2001

Mr. Michael Carroll
President & CEO
TeleMed Systems, Inc.
8 Kane Industrial Drive
HUDSON MA 01749

Re: K010412
Flexible Endoscopic Scissors
Dated: February 1, 2001
Received: February 12, 2001
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Mr.Carroll:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010412

Device Name: TeleMed Systems, Inc. Flexible Endoscopic Scissor

Indications for Use:

The TeleMed Systems, Inc. Flexible Endoscopic Scissors are indicated for use for cutting of tissue when used through the working channel of a flexible or rigid endoscope.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010412